K002828

OCT 17 2000

510(k) Summary

1.0 Date Prepared

October 13, 2000

2.0 Submitter (Contact)

Martin D. Sargent
Regulatory Affairs Manager
Medtronic Xomed
Jacksonville, FL
(904) 279-7586

3.0 Device Name

Proprietary Name:	XPS Nitro
Common Name(s):	Pneumatic surgical drill, mastoid drill, ENT drill, handpiece, accessories, and cutting burs
Classification Name(s):	Drill, surgical, ENT (electric or pneumatic) including handpiece

4.0 Device Classification

Classification Name: Drill, surgical, ENT (electric or pneumatic) including handpiece
Procode: 77ERL Class II 21 CFR § 874.4250

5.0 Device Description

The XPS Nitro system consists of a pneumatic hose, footswitch, and handpiece. The handpiece drives a variety of dissecting burs and drills. Various attachments are available to stabilize dissecting burs and provide irrigation. A twist drill attachment provides adjustable hole depth. The system may be connected to a hospital nitrogen supply or to a nitrogen tank via an optional regulator.

6.0 Indications for Use

The XPS Nitro is indicated for the incision and removal of soft and hard tissue or bone in general otorhinolaryngology, head and neck, and otoneurological procedures, including mastoidectomy and mastoidotomy.

7.0 Substantial Equivalence

The XPS Nitro is substantially equivalent to the Medtronic Xomed ACE drill system as described in K960853 in its intended use, function, and performance characteristics.

Characteristic	**XPS Nitro (Proposed)**	**Xomed ACE (K960853)**
Intended use	Controlled incision or removal of bone	Controlled incision or removal of bone
Maximum speed	65,000 RPM	70,000 RPM
Drill power	Pneumatic	Electrical
Footswitch type	Pneumatic speed control	Electrical speed control
Handpiece autoclavable	Yes	Yes
Handpiece flash autoclavable	Yes	Yes
Drill collet design	Collet designed for Xomed Notched burs	Collet designed for Xomed Notched burs
Bur irrigation available	Yes	Yes
Irrigant supply	Supplied by external pump	Supplied by integral pump on drill console

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2000

Mr. Martin D. Sargent
Regulatory Affairs Manager
Medtronic Xomed, Inc.
6743 Southpoint Dr. North
Jacksonville, FL 32216

Re: K002828
Trade Name: XPS Nitro System
Regulatory Class: II
Product Code: 77 ERL
Dated: September 8, 2000
Received: September 11, 2000

Dear Mr. Sargent:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K002828

Device Name: XPS Nitro

Indications for Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K002828

Prescription Use ✓ Or Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)